

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BARDY DIAGNOSTICS, INC.,)	
)	
Plaintiff, Counter-Defendant)	
)	
v.)	C.A. No. 24-1355 (JDW)
)	
IRHYTHM TECHNOLOGIES, INC.,)	
)	
Defendant, Counter-Plaintiff.)	

**OPENING BRIEF IN SUPPORT OF DEFENDANT AND COUNTERCLAIM-
PLAINTIFF IRHYTHM TECHNOLOGIES, INC.'S MOTION FOR LEAVE TO FILE
FOURTH AMENDED COUNTERCLAIMS AND ANSWER**

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Defendant and Counterclaim-Plaintiff iRhythm Technologies, Inc. (“iRhythm”) respectfully requests leave to file its Fourth Amended Counterclaims and Answer against Plaintiff and Counterclaim-Defendant Bardy Diagnostics, Inc. (“Bardy”) pursuant to Federal Rules of Civil Procedure 15(a)(2) and 16(b)(4). iRhythm’s Fourth Amended Counterclaims and Answer (Exhibit A) and corresponding redline pursuant to D. Del. LR 15.1 (Exhibit B) are attached to this Motion.

I. INTRODUCTION

The United States Patent and Trademark Office (“USPTO”) issued iRhythm’s Patent No. 12,402,819 (the “’819 patent”) on September 2, 2025, and has stated that it will issue iRhythm’s U.S. Patent No. 12,408,856 (the “’856 patent”) on September 9, 2025.¹ iRhythm’s proposed amended counterclaims seek only to accuse Bardy’s CAM patch – the Bardy product already at issue in this litigation – of infringement. There is no doubt that iRhythm has every legal right to accuse Bardy of infringing its patents upon issuance, as Bardy has already done with four of its patents. The only question is whether those allegations will be part of this litigation or a separate one.

Under controlling law, leave to amend “shall be freely given when justice so requires,” as it does here. iRhythm’s proposed counterclaims are accusations that the single Bardy product already accused of infringement in this litigation (the Bardy CAM patch) infringes two patents related to patents already asserted in this litigation (the Kumar and Bahney families). There will be substantial efficiencies gained through amendment as compared to a separate lawsuit, as the

¹ iRhythm does not enclose the patents or related claim charts noted in its proposed amended counterclaims (Exhibit A). These documents have been served on Bardy in conjunction with the filing of this motion, except for the ’856 patent that will issue on September 9, 2025. To the extent iRhythm’s motion is granted, iRhythm will file its proposed amended counterclaims with all underlying exhibits.

case will involve minimal additional discovery and only minor modifications to the case schedule (limited to claim construction briefing), which remains in its early stages. Indeed, discovery is not scheduled to close for eleven months, in July of 2026. For the same reasons, there is no countervailing evidence of undue prejudice to Bardy, nor undue delay or bad faith by iRhythm.

The concern raised by Bardy at the status conference – that iRhythm delayed too long to seek the now-allowed claims – does not demonstrate any undue delay or bad faith. Bardy itself continued to prosecute patent claims after it launched this litigation and then sought to add them to this case via amendment, an action iRhythm did not oppose. If anything, Bardy’s very initiation of this litigation represents dilatory behavior in obtaining patent protection as the patents from Bardy’s Complaint and First Amended Complaint stemmed from patent applications Bardy filed in August 2024, six months after its sister company Welch Allyn, Inc., represented by the same outside counsel, sued iRhythm for patent infringement. There is no bad faith or undue delay on iRhythm’s part.

Leave to amend should be granted.

II. NATURE AND STAGE OF PROCEEDING

This is a patent infringement case initially filed by Bardy on December 10, 2024. Bardy originally asserted that iRhythm infringed a single patent but has twice amended the pleadings to allege infringement by iRhythm of three additional patents. D.I. 1, D.I. 9, D.I. 52. In response, iRhythm has filed counterclaims asserting that Bardy and its CAM patch infringe five iRhythm patents. *See, e.g.*, D.I. 12, D.I. 43, D.I. 56. Most recently, the parties filed a joint motion in June 2025 in which Bardy asserted infringement of two patents and iRhythm added a counterclaim for one additional patent. *See* D.I. 48. The Court granted this joint motion on June 11, 2025. D.I. 51.

The deadline to amend or supplement the pleadings was June 2, 2025. D.I. 29. Substantial completion of document production is scheduled for October 24, 2025, a *Markman* hearing is

scheduled for January 15, 2026, and discovery does not close until July 17, 2026. *Id.* Trial is not scheduled. *Id.*

III. SUMMARY OF THE ARGUMENT

1. Under Fed. R. Civ. P. 15(a), leave to amend “shall be freely given when justice so requires,” a consideration present here due to the efficiencies gained because this case already involves claims that the accused product (the Bardy CAM patch) infringes patents related to those iRhythm seeks leave to assert.

2. Further, under Fed. R. Civ. P. 15(a), there is no undue prejudice, undue delay or bad faith as this action remains in its early stages, the schedule can be readily modified to accommodate the additional patents, and numerous patents have already been added to this action via amendment.

3. Under Fed. R. Civ. P. 16(b), good cause exists to grant iRhythm’s leave to amend because iRhythm diligently sought additional patent protection upon Bardy’s initiation of this lawsuit and filed this motion shortly after learning of the issuance dates for the patents from the USPTO.

IV. STATEMENT OF FACTS

On February 20, 2024, Welch Allyn, Inc. (“Welch Allyn”) sued iRhythm for infringement of four patents in the matter of *Welch Allyn, Inc. v. iRhythm Technologies, Inc.*, C.A. No. 24-224-MN (D. Del. Feb. 20, 2024).

Six months later, on August 12, 2024, Bardy (Welch Allyn’s sister company through its corporate parent, Baxter International, Inc.) filed the patent application that would issue as U.S. Patent No. 12,161,473. Shortly thereafter, on August 30, 2024, Bardy filed the patent application that would issue as U.S. Patent No. 12,171,562. Upon issuance of U.S. Patent No. 12,161,473 on

December 10, 2024, Bardy asserted it against iRhythm, initiating this litigation. Shortly thereafter, Bardy amended its claims to assert U.S. Patent No. 12,161,562.

Bardy then continued to prosecute additional applications related to these two patents, including amending pending claims on March 27, 2025 in an application that would issue as U.S. Patent No. 12,310,735. Exhibit C. Upon issuance, Bardy sought to assert U.S. Patent No. 12,310,735, as well as U.S. Patent No. 12,285,261, against iRhythm. iRhythm did not oppose Bardy's request to add these new patents, and they were added to the case on June 11, 2025. All four Bardy patents are from the same family, the "Felix" family, and claim priority to a common provisional patent application, filed on September 25, 2013.²

Bardy sells a cardiac monitor in the United States, the Bardy CAM patch. After Bardy launched this lawsuit, iRhythm reviewed its patent portfolio, and asserted five patents against Bardy, accusing the Bardy CAM patch of infringement. All of these patents have been asserted in this litigation, and they all stem from one of two families, the "Kumar" family, claiming priority to May 12, 2010, and the "Bahney" family, claiming priority to January 24, 2013.

As both the Kumar and Bahney family disclosed numerous inventive contributions deserving of patent protection, iRhythm sought additional patent protection during pendency of this litigation, just like Bardy. On May 19, 2025, iRhythm filed U.S. Patent App. No. 19/212,547 in the Kumar family and U.S. Patent App. No. 19/212,582 in the Bahney family. These applications have issued, or will soon issue, as the '856 and '819 patents, respectively.

The '819 patent is titled "Physiological Monitoring Device." It claims a body-worn device configured to monitor cardiac rhythm data. Similar to the other Bahney patents, the claimed device

² Although the four Bardy patents all claim priority to the September 25, 2013 provisional application, additional subject matter was added later and iRhythm reserves all rights to challenge entitlement to any priority date.

comprises certain components, such as a housing, a flexible layer, a trigger, and electrodes. It additionally claims particular configurations and arrangements for the flexible layer, the trigger, the electrodes, and supporting electrical connections, among other things.

The '856 patent will be titled "Device Features and Design Elements for Long-term Adhesion." It will claim a wearable cardiac signal monitoring device with components such as a housing, a flexible layer, a printed circuit board, and electrodes, similar to the other Kumar patents. It additionally claims a removable component for data processing and specifics about the flexible layer, the printed circuit board, and the electrodes, among other things.

Shortly after the USPTO notified iRhythm that the claims of the applications that would issue as the '819 and '856 patents would be allowed, iRhythm informed Bardy on July 30, 2025 that it intended to amend its pleadings to assert these two additional patents. *See* Exhibit D. iRhythm provided Bardy the allowed claims on August 11, 2025. *See* Exhibit E. On August 13, 2025, iRhythm notified the Court of its intention to seek leave to amend in advance of the August 14, 2025 status conference, and this matter was discussed during that status conference. *See* Exhibit F (D.I. 76).

The USPTO issued iRhythm's U.S. Patent App. No. 19/212,582 as the '819 patent on September 2, 2025, and has notified iRhythm that U.S. Patent App. No. 19/212,547 will issue as the '856 patent on September 9, 2025. On September 3, 2025, iRhythm notified Bardy of its willful infringement of these patents and, on September 5, 2025, filed this Motion.

V. ARGUMENT

A. Leave to Amend is Appropriate Here, As Amendment Is the Most Efficient Path for the Parties and the Court, and There is No Undue Prejudice, Undue Delay, or Bad Faith to Bar Amendment

Under Fed. R. Civ. P. 15(a), leave to amend "shall be freely given when justice so requires." In Delaware, the dispositive factor is prejudice to the non-moving party – here, Bardy. *See*

Cordance Corp. v. Amazon.com, Inc., 255 F.R.D. 366, 371 (D. Del. 2009). Leave to amend should be granted absent a showing of “undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of the allowance of the amendment, futility of amendment, etc.” *Foman v. Davis*, 371 U.S. 178, 182 (1962); see *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1434 (3d Cir. 1997). Bardy “must do more than merely claim prejudice; it must show that it was unfairly disadvantaged or deprived of the opportunity to present facts or evidence which it would have offered had the amendments been timely.” *In re Burlington*, 114 F.3d 1410 at 1434 (citing *Bechtel v. Robinson*, 886 F.2d 644, 652 (3d Cir.1989)); see also *SunPower Corp. v. PaneClaw, Inc.*, C.A. No. 12-1633-MPT, 2016 WL 5107029, at *7 (D. Del. Sept. 19, 2016).

Asserting the ’819 and ’856 patents at this stage of the case promotes justice and efficiency for both the Court and the parties. These patents stem from the same families as already-asserted patents, claim similar subject matter as those patents, and iRhythm’s infringement allegations implicate the same Bardy product of infringement, minimizing any risk of undue prejudice. Granting iRhythm leave to amend would also avoid unnecessarily expending judicial resources, costs, and time on a separate case against Bardy on the Court’s docket. Accordingly, granting iRhythm’s leave to amend is necessary for efficiently litigating infringement claims of iRhythm’s related patents, maintaining substantially similar discovery, and avoiding the burdens on the Court and the parties involved in litigating these claims in a separate case.

There is no prejudice to Bardy, and certainly no unfair disadvantage or deprivation of opportunity. First, due to the common subject matter between the new patents and the current asserted patents, and the common accused Bardy product, there is little additional discovery or

document production that will be needed to account for these new patents. Second, the addition of two new patents does not constitute any unfair disadvantage or deprivation of the opportunity to present facts or evidence to Bardy, as discovery is not set to close until July 17, 2026, claim construction briefing has yet to begin, and substantial completion of document production is scheduled for October 24, 2025. Courts in this district have found no unfair disadvantage or deprivation of opportunity when a motion to amend the pleading was filed as little as two months prior to close of fact discovery. *Research Found. of State Univ. of N.Y. v. Mylan Pharm. Inc.*, C.A. No. 09-184-GMS-LPS, 2010 WL 2572715, at *3 (D. Del. June 28, 2010). Here, Bardy will have 11 months remaining in discovery to present any facts or evidence in response to the addition of two new patents to the case. Accordingly, Bardy cannot show any disadvantage or deprivation of opportunity. *SunPower*, 2016 WL 5107029, at *7.

The only adjustment to the schedule that may be necessary is an adjustment to the claim construction briefing schedule, an issue that only arises if Bardy seeks to construe additional terms from these two new patents. In that situation, iRhythm does not object to a reasonable number of additional terms or phrases for construction, such as one per patent (i.e., two total), consistent with the Court's present Scheduling Order allowing ten total terms for construction across nine patents, and the Court setting a reasonable standard for stand-alone supplemental briefing. D.I. 29. As an example, iRhythm has attached a potential schedule for the Court's consideration to accommodate briefing on any additional terms. *See* Ex. G.³

There is also no undue delay, bad faith or dilatory motive in amending the pleading to add two new patents. iRhythm promptly notified Bardy on July 30, 2025 of its intention to amend

³ iRhythm intends to serve infringement contentions for the two new patents next week regardless of the outcome of this Motion, as indicated in the proposed schedule.

the pleadings and sent Bardy a copy of the allowed claims on August 11, 2025. *See* Exhibits D and E. iRhythm then moved to amend its pleading shortly after the first patent issued, and even before the issuance date of the second patent.

At the August 14, 2025 status conference, Bardy's counsel argued that iRhythm unduly delayed or engaged in bad faith in filing the patent applications that have issued, or will issue, as the '819 and '856 patents. This is not bad faith. iRhythm has every right to seek patent protection and to assert those patents against those who infringe. Nor is it undue delay, as iRhythm filed the patent applications just a few months after Bardy initiated this lawsuit.

Indeed, Bardy's own actions demonstrate the lack of bad faith and undue delay. Bardy itself continued to prosecute and tailor its patents after it brought this lawsuit. For example, on March 27, 2025, over three months after *Bardy* initiated this action, Bardy rewrote then-pending claims to obtain what would issue as U.S. Patent No. 12,310,735, which it then asserted in June 2025. *See* Exhibit C. Similarly, Bardy only filed the patent applications that became the foundation of this lawsuit, U.S. Patent Nos. 12,161,473 and 12,171,562, in August 2024, six months after its sister company Welch Allyn sued iRhythm for patent infringement. Bardy cannot claim ignorance of Welch Allyn's actions as the two sister companies share the same team of outside counsel at K&L Gates, and Bardy's patent applications have been filed by patent prosecutors at K&L Gates. Given Bardy's delay in obtaining patent protection while having knowledge of Welch Allyn's patent infringement case and *its own intent to bring litigation*, iRhythm was not afforded the same opportunity to execute its prosecution strategies. Nevertheless, iRhythm has acted diligently to obtain its own patent protection and assert its own patents.

B. Good Cause Exists Because iRhythm Has Diligently Acted to Assert Its Newly Issued Patents

Under Fed. R. Civ. P. 16(b), good cause “requires the movant to demonstrate that, despite diligence, the proposed claims could not have been reasonably sought in a timely manner.” *Cordance*, 255 F.R.D. 366 at 371. “In contrast to Rule 15(a), the good cause standard under Rule 16(b) hinges on diligence of the movant, and not on prejudice to the non-moving party.” *Id.*

Here, good cause exists because iRhythm diligently filed this motion for leave as soon as the notices of issuance were filed. Other courts in this district have found diligence when the motion to amend was filed up to three months after learning the new information, which squarely supports iRhythm’s motion in this case. *See Home Semiconductor Corp. v. Samsung Elecs. Co.*, C.A. No. 13-2033-RGA, 2019 WL 2135858, at *3 (D. Del. May 16, 2019); *see also Intell. Ventures I LLC v. Toshiba Corp.*, C.A. No. 13-453-SLR, 2016 WL 4690384, at *1 (D. Del. Sept. 7, 2016). iRhythm would not have been legally authorized to amend its pleading *before* the USPTO sent the notices of issuance for the patents. Rather than waiting for the issuance date for the ’856 patent, iRhythm filed this motion to amend immediately after being informed of the notice of issuance. iRhythm’s diligence establishes good cause to amend.

VI. CONCLUSION

For all the reasons set forth above, iRhythm respectfully requests that the Court grant its motion for leave to file its Fourth Amended Counterclaims and Answer.

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CERTIFICATE OF SERVICE

I hereby certify that on September 5, 2025, I electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused to be served copies of the foregoing document on September 5, 2025, upon the following in the manner indicated:

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